

# The interplay of global standards and EU pharmaceutical regulation

Citation for published version (APA):

Röttger-Wirtz, S. (2017). *The interplay of global standards and EU pharmaceutical regulation*. [Doctoral Thesis, Maastricht University]. Maastricht University. <https://doi.org/10.26481/dis.20171218sr>

## Document status and date:

Published: 01/01/2017

## DOI:

[10.26481/dis.20171218sr](https://doi.org/10.26481/dis.20171218sr)

## Document Version:

Publisher's PDF, also known as Version of record

## Please check the document version of this publication:

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## Propositions

1. Global standard-setting is an increasingly important phenomenon, the impact of which is often hidden behind the technical and scientific nature of standards as regulatory measures.
2. Global pharmaceutical standards set by the International Council on Harmonisation substantially shape the regulation of pharmaceuticals in the EU.
3. Legitimacy flaws in the standard-setting process on the global level are inherently carried over to the EU through the implementation of such standards.
4. The participation of European bodies, and especially European agencies, in global standard-setting initiatives and the implementation of such standards in the EU are currently not subject to a coherent legal framework within the Union.
5. Gaps with regard to the political and judicial accountability for the implementation of these standards in the EU persist.
6. The EU's commitment towards values of good governance is incomplete as long as it does not include the global standards implemented in the EU.
7. Where the legal scholarship limits its analysis to legally binding measures, neglecting soft law regulatory tools, it opens the door to undermining the procedural rules that protect the legitimacy of risk regulation measures.
8. Although a coherent body of global or international administrative law, governing the exercise of global regulatory power is currently lacking, EU administrative law can offer examples of best-practices to the development of such a body of law on the global level.
9. The alternative to a fact is illusion. The alternative to illusion is the creation of knowledge. The creation of knowledge is a value in and of itself.
10. Academic research is a never-ending challenge to presumptions – those with regard to the field of your study as well as presumptions you hold about yourself. As John Williams said about his novel character Stoner: “It was himself that he was attempting to define as he worked on his study. It was himself that he was slowing shaping, it was himself that he was putting into a kind of order, it was himself that he was making possible.”